Alcala LABS

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ACCESSION STICKER HERE

RESPIRATORY PANEL AND SARS-COVID-19 TEST REQUISITION FORM

PATIENT INFORMATION

Last Name _____ First Name _____ MI _____

Gender: ☐ M ☐ F ☐ M/F ☐ F/M Date of Birth ____/____/_____

Patient Address _____

City, State, ZIP code **Contact Information (E-mail & Phone)** _____

Occupation/Exposure setting: _____

Pregnancy Status: ☐ Yes ☐ No ☐ N/A

Race: ☐ Amer Ind/Alaskan ☐ White ☐ Black/Afr Amer
☐ Asian ☐ Native Hawaiian/Pacific Islander ☐ Other

PROVIDER INFORMATION

Facility/Group _____ Referring Physician _____

NPI Provider Nr: _____

Physician Address _____

City, State, ZIP code _____

Diagnostic Codes (ICD-10 codes*** see Page 3) _____

*Clinical Information** (date of onset/exposure, travel history, previous lab results – attach additional info.)* _____

Ethnicity: ☐ Hispanic/Latino ☐ Non-Hispanic/Non-Latino ☐ Other

Billing information: ☐ Self-Pay (see Page 2) ☐ Commercial Insurance (attach copy) ☐ Medicare (attach copy)

COVID-19 Serum ANTIBODY test (check all that apply):

☐ IgG ☐ IgM

SAMPLE HANDLING

Time Collected: _____ AM/PM Date Collected: _____

Collected by: _____

The following ***MUST*** be completed (check all that apply):
☐ Clinical Information provided.
☐ **Serum (SST tube) venipuncture draw vacutainer tube placed in dry ice shipping box and in biohazard bag** (labeled with patient information – First/Last Name, DOB): ensure 30 minute clot time is allowed, centrifuge tube 10-15 minutes depending on centrifuge used, store at 4°C prior to transport.

INFORMED CONSENT

I consent to the collection of specimens for the purpose of DNA testing, and certify that the tests ordered have been explained to me by an authorized health care provider. I understand that only tests ordered by a qualified provider will be performed. This sample may be stored indefinitely and used for internal test validation after personal identifiers have been removed. I also authorize lab to bill my insurance provider and to receive payment of benefits for the tests ordered by my physician. I further authorize lab and the ordering physician to release to my insurance provider any medical information necessary to process this claim. I acknowledge that lab may be an out-of-network facility with my insurance provider.

Signature of Patient or Legal Guardian:
If Guardian, Print Name:
Date:

PROVIDER INFORMATION

I attest that the requested testing is medically necessary and appropriate based on the patient's diagnosis and treatment plan. I have personally completed the diagnosis codes above to indicate the accurate diagnosis for this patient.

Authorized Provider Signature:

Date:

BILLING INFORMATION

☐ Insurance Bill ☐ Account Bill ☐ Patient Bill ☐ Pre-Pay (Payment Information must be completed)

Ordering Physicians should refer to applicable National and Local Coverage Determinations for further information concerning reimbursement policy. Tests submitted for Medicare and Medicaid reimbursement must meet program requirements (ICD10-codes required) or the claim may be denied.

Bill Ordering Institution: Bill Insurance:

(Provide legible photocopy of front & back of insurance card)

Name of Insured: Relation to Patient: Insurance Company: Member

Social Security #: Member Group #: Insurance Address: Member Policy #:

Insurance Phone:

PAYMENT INFORMATION (PRE-PAY)

Check Card Used for Payment: ☐ VISA ☐ MasterCard ☐ American Express ☐ Discover

Card Number: Card Security Code:

Signature: Exp. Date:

(**) Priority COVID-19 Testing Groups if mild/moderate symptoms observed (Fever, Cough, etc.):

- Evidence of lower respiratory disease without alternative diagnosis, especially if hospitalized
- Any resident of a senior living facility, including skilled nursing facilities or assisted living facilities
- Persons who care for the elderly
- Persons living in congregate setting (homeless shelters, etc.)
- Health care workers, first responders, and other emergency workers

Test information:

EDI™ Novel Coronavirus COVID-19 IgG or IgM ELISA kits: *This ELISA kit is designed, developed, and produced for the qualitative measurement of the human anti-COVID-19 IgG/IgM antibody in serum. This assay utilizes the microplate based enzyme immunoassay technique.*

Assay controls and 1:100 diluted human serum samples are added to the microtiter wells of a microplate that was coated with COVID recombinant full length nucleocapsid protein. After the first incubation period, the unbound protein matrix is removed with a subsequent washing step. A horseradish peroxidase (HRP) labeled polyclonal goat anti-human IgG or IgM tracer antibody is added to each well. After an incubation period, an immunocomplex of "COVID-19 recombinant antigen – human anti-COVID-19 IgG or IgM antibody - HRP labeled antihuman IgG tracer antibody" is formed if there is specific coronavirus IgG or IgM antibody present in the tested specimen. The unbound tracer antibody is removed by the subsequent washing step. HRP tracer antibody bound to the well is then incubated with a substrate solution in a timed reaction and then measured in a spectrophotometric microplate reader. The enzymatic activity of the tracer antibody bound to the anti-COVID-19 IgG or IgM on the wall of the microtiter well is proportional to the amount of the anti-COVID-19 IgG antibody level in the tested specimen.

EUA-approval for the ELISA IgG/IgM kits was submitted to the FDA on March 05, 2020 for Emergency Use Authorization (EUA) and are assigned the number PEUA200035.

***** ICD10 Codes:**

SARS-CoV-2:

U07.1 COVID-19
Z20.828 Contact with and (suspected) exposure to other viral communicable diseases

General Respiratory Virus:

B30.2 Viral pharyngoconjunctivitis
B34.0 Adenovirus infection, unspecified
B34.2 Coronavirus infection, unspecified
B97.0 Adenovirus as the cause of diseases classified elsewhere
B97.21 SARS-associated coronavirus. cause of diseases classified elsewhere
B97.29 Other coronavirus as the cause of diseases classified elsewhere
B97.4 Respiratory syncytial virus as the cause of diseases classified elsewhere
B97.81 Human metapneumovirus as the cause of diseases classified elsewhere
B97.89 Other viral agents as the cause of diseases classified elsewhere
J00 Acute nasopharyngitis [common cold]
J05.0 Acute obstructive laryngitis [croup]
J06.9 Acute upper respiratory infection, unspecified
J09.X1 Influenza due to identified novel influenza A virus with pneumonia
J09.X2 Influenza due to identified novel influenza A virus with other respiratory manifestations
J09.X3 Influenza due to identified novel influenza A virus with gastrointestinal manifestations
J09.X9 Influenza due to identified novel influenza A virus with other manifestations
J10.00 Influenza due to other identified influenza virus with unspecified type of pneumonia
J10.01 Influenza due to other identified influenza virus with the same other identified influenza virus pneumonia
J10.08 Influenza due to other identified influenza virus with other specified pneumonia
J10.1 Influenza due to other identified influenza virus with other respiratory manifestations
J10.2 Influenza due to other identified influenza virus with gastrointestinal manifestations
J10.81 Influenza due to other identified influenza virus with encephalopathy
J10.82 Influenza due to other identified influenza virus with myocarditis
J10.83 Influenza due to other identified influenza virus with otitis media
J10.89 Influenza due to other identified influenza virus with other manifestations
J11.00 Influenza due to unidentified influenza virus with unspecified type of pneumonia
J11.08 Influenza due to unidentified influenza virus with specified pneumonia
J11.1 Influenza due to unidentified influenza virus with other respiratory manifestations
J11.2 Influenza due to unidentified influenza virus with gastrointestinal manifestations
J11.81 Influenza due to unidentified influenza virus with encephalopathy
J11.82 Influenza due to unidentified influenza virus with myocarditis
J11.83 Influenza due to unidentified influenza virus with otitis media
J11.89 Influenza due to unidentified influenza virus with other manifestations
J12.0 Adenoviral pneumonia
J12.1 Respiratory syncytial virus pneumonia
J12.2 Parainfluenza virus pneumonia
J12.3 Human metapneumovirus pneumonia
J12.81 Pneumonia due to SARS-associated coronavirus
J12.9 Viral pneumonia, unspecified
J20.4 Acute bronchitis due to parainfluenza virus
J20.5 Acute bronchitis due to respiratory syncytial virus
J20.6 Acute bronchitis due to rhinovirus
J21.0 Acute bronchiolitis due to respiratory syncytial virus
J21.9 Acute bronchiolitis, unspecified
J22 – Unspecified acute lower respiratory infection
Z11.59 Encounter for screening for other viral diseases

Pneumonia:

A49.3 Mycoplasma infection, unspecified site
B96.0 Mycoplasma pneumoniae [M. pneumoniae] as the cause of diseases classified elsewhere
J15.7 Pneumonia due to Mycoplasma pneumoniae
J20.0 Acute bronchitis due to Mycoplasma pneumoniae
Z11.2 Encounter for screening for other bacterial diseases